K121888

JUL 26 2012

510(k) Summary

In accordance with 21CFR807.92, the following summary of information is provided;

Date	June 26th 2012
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848,
Primary Contact Person	Donghwan Kim QARA Manager Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848, Phone: +82 70 7465 2068 Fax: +82 2 851 5594 Email: donghwan.kim@alpinion.com
Secondary Contact Person	Yuchi Chu Address: Suite 229, 10604 NE 38th Place, Kirkland, WA 98033, United States Phone: 425 949 4907 Fax: 425 949 4908 Email: ychu@alpinionus.com
Device Trade Name:	E-CUBE 15
Common/Usual Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Names	System, Imaging, Pulsed Doppler Ultrasonic
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO, IYN Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX
Predicate Device(s)	K120060 E-CUBE 9 Diagnostic Ultrasound System

Device Description: E-CUBE 15 product is an ultrasound imaging system for medical diagnosis. The system platform provides optimal patient diagnosis workflow with the 18.5" wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

Indications For Use: The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV); and Urology (including prostate).

Technology: E-CUBE 15 employs the same fundamental scientific technology as its predicate device.

Feature	Proposed E-CUBE 15 ALPINION MEDICAL SYSTEMS Co., Ltd.	Predicate E-CUBE 9 ALPINION MEDICAL SYSTEMS Co., Ltd.
510(k) Number	-	K120060
Indications for use	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal Superficial); Cardiac (adult); Peripheral Vascular (PV); Urology (including prostate).	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult & pediatric); Peripheral Vascular (PV); Urology (including prostate).
	• Discussion of differences The individual functions of E-CUBE 15 has essential performance and safety effectiveness same as E-CUBE 9, even though E-CUBE 15 as limited scope of the indications comparing with the predicate. Therefore, E-CUBE 15 substantially equivalent with predicate device.	
Dimensions and weight	Weight: approx. 105kg Height: 1413/1848 mm Width: 585mm Depth: 670mm	Weight: approx. 89.5kg Height: 1340/1600 mm Width: 590mm Depth: 850mm

Monitor	18.5" Wide LCD Display size: 1366 X 768 Recording area: 880 X 660 Adjustable Tilt/Swivel, up/down, rotate Digital Brightness/Contrast Adjustment	17" Wide LCD 18.5" Wide LCD Display size: 1366 X 768 Recording area: 880 X 660 Adjustable Tilt/Swivel, up/down, rotate Digital Brightness/Contrast Adjustment
Electrical power	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board Peripherals	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 600 VA with Built-in and On-Board Peripherals
Consol design	• 3 active Probe Ports (4 Probe Ports Option) • Touch panel • Integrated HDD (Capacity: 500G) • Integrated DVD-R/W Drive • On-board Storage for Peripherals - B/W Printer Color Printer, DVD recorder • Control panel lift mechanism • 5 Transducer holders, detachable for cleaning and washing • Integrated Gel warmer - 3 temperature levels • Front Handle • Rear Handle • Wheel-lock Mechanism - Front & Back –Wheel: Total lock • 8 USB ports: Touch module side (2ea) Back side (6ea) • Thumbnail images on-screen • On-line Help key • ECG Module • Patient ECG Lead Wires	• 3 active Probe Ports • Integrated HDD (Capacity: 500G) • Integrated DVD-R/W Drive • On-board Storage for Peripherals - B/W Printer Color Printer, DVD recorder • Control panel lift mechanism • 5 Transducer holders, detachable for cleaning and washing • Integrated Gel warmer - 3 temperature levels • Front Handle • Rear Handle • Wheel-lock Mechanism - Front & Back –Wheel: Total lock • 5 USB ports: Front Side (1ea) Back side (6ea) • Thumbnail images on-screen • On-line Help key • ECG Module • Patient ECG Lead Wires
	● Discussion of differences E-CUBE 15 has 3 or 4 (optional) probe ports, 8 USB ports: Touch module side (2ea) Back side (6ea) and Touch panel. But, E-CUBE 9 has 3 probe ports and 5 USB ports: Front Side (1ea) Back side (6ea). It is not related with the safety, effectiveness and essential performance.	
Operating Mode	• B-Mode • M-Mode • Anatomical M-mode • Pulsed Wave (PW) Doppler with High PRF • Continuous Wave (CW) Doppler • Color Flow-Mode	• B-Mode • M-Mode • Anatomical M-mode • Pulsed Wave (PW) Doppler with High PRF • Continuous Wave (CW) Doppler • Color Flow-Mode

	• Power Doppler Mode • THI (PI/FTHI) • Tissue Doppler Imaging • Beam Steering • Panoramic B/CF • Spatial compounding • Frequency compounding • Xpeed on 2D / CF/PW • Auto IMT • Auto traces PW • Directional Power Doppler Mode • SRI • Full SRI • ECG	• Power Doppler Mode • THI (PI/FTHI) • Tissue Doppler Imaging • Beam Steering • Panoramic B/CF • Spatial compounding • Frequency compounding • Xpeed on 2D / CF/PW • Auto IMT • Auto traces PW • Directional Power Doppler Mode • SRI • Full SRI • ECG • 3D/4D Volume Mode
	● Discussion of difference 3D/4D is an image representation of a volume or 3D object, such as the heart or fetus. Surface rendering can be used to visualize surfaces. Another image presentation is volume rendering, in which surfaces can be semitransparent or 2D slice planes through the object. Alternatively, there is simultaneous viewing of different 2D slice planes (side by side). E-CUBE 15 includes essential operating mode for diagnosis and is Substantially Equivalent.	
Labeling and/or promotional materials	Section 6B Catalog E-CUBE 15	Section 3C Catalog E-CUBE9
Accessories or kits	Color printer B/W printer DVR DVD –RW Footswitch Probe Holder Ultrasonic gel Cidex OPA (disinfectant agents) Cidex Plus (disinfectant agents) SC1-6 Biopsy guide kit L3-12 Biopsy guide kit E3-10 Reusable Biopsy needle guide E3-10 Disposable Biopsy needle guide ECG Module Patient ECG Lead Wires	Color printer B/W printer DVR DVD –RW Footswitch Probe Holder Ultrasonic gel Cidex OPA (disinfectant agents) Cidex Plus (disinfectant agents) SC1-6 Biopsy guide kit L3-12 Biopsy guide kit E3-10 Reusable Biopsy needle guide E3-10 Disposable Biopsy needle guide ECG Module Patient ECG Lead Wires

Measurement and Calculation functions	1. General 1) B-Mode 2) M-Mode 3) Doppler Mode	1. General 1) B-Mode 2) M-Mode 3) Doppler Mode
	2. Abdomen 1) B-Mode 2) M-Mode 3) Doppler Mode	2. Abdomen 1) B-Mode 2) M-Mode 3) Doppler Mode
	3. Small Parts 1) B-Mode 2) M-Mode 3) Doppler Mode	3. Small Parts 1) B-Mode 2) M-Mode 3) Doppler Mode
	4. Obstetrics 1) B-Mode 2) M-Mode: 3) Doppler Mode	4. Obstetrics 1) B-Mode 2) M-Mode: 3) Doppler Mode
	5. Gynecology 1) B-Mode 2) M-Mode: 3) Doppler Mode	5. Gynecology 1) B-Mode 2) M-Mode: 3) Doppler Mode
	6. Cardiology 1) B-Mode: 2) M-Mode 3) Doppler Mode	6. Cardiology 1) B-Mode: 2) M-Mode 3) Doppler Mode
	7. Vascular 1) B-Mode 2) M-Mode 3) Doppler Mode	7. Vascular 1) B-Mode 2) M-Mode 3) Doppler Mode
	8. Urology 1) B-Mode 2) M-Mode 3) Doppler Mode	8. Urology 1) B-Mode 2) M-Mode 3) Doppler Mode
		9. Pediatrics 1) B-Mode 2) M-Mode 3) Doppler Mode
	• Discussion of difference Measurement and Calculation functions of E-CUBE 15 are not include Pediatrics. It is not related with the safety, effectiveness and essential performance.	
Acoustic output	Track 3	Track 3

<Conclusion>

The indications for use, material, form factor, performance, and safety characteristics between E-CUBE 15 and the predicate device are the same except for Pediatric, Cardiac (pediatric). The primary difference is cosmetic structure and component used only. Therefore, we can claim the substantially equivalence of E-CUBE 15 to the predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

E-CUBE 15 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 15 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 15:

- NEMA UD2, UD3
- AIUM Medical Ultrasound Safety
- IEC60601-1
- IEC60601-1-2
- IEC60601-2-37 (3rd Edition)
- ISO 10993-1

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 15, did not require clinical studies to support substantial equivalence.

Conclusion: Alpinion Medical Systems Co., Ltd. considers E-CUBE 15 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.

Appendix B – Decision Summary for Web Posting

Decision Summary, K 121888

This 510(k) was reviewed under OIVD's Pilot Triage Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Donghwan Kim
QARA Manager
Alpinion Medical Systems Co., Ltd.
1, 6, and 7FL Verdi Tower
72, Digital-ro (St) 26-gil (Rd), Guro-gu
SEOUL 152-848
REPUBLIC OF KOREA

SEP 25 2012

Re: K121888
Trade/Device Name: E-CUBE 15
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: June 26, 2012
Received: June 28, 2012

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of July 26, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the E-CUBE 15, as described in your premarket notification:

Transducer Model Number	
SC1-6H	L8-17X
L3-12H	SC1-4H
SP1-5X	E3-10H

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

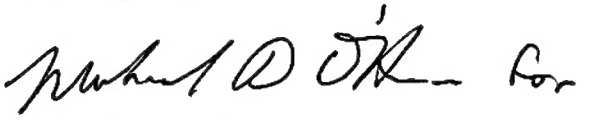
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: E-CUBE 15

Indications for Use:

The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Small Organ (breast, testes, thyroid); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV); and Urology (including prostate).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	N	N	N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	N	N	N		N	N	N	N	
Musculo-skeletal (*Superficial*)	N	N	N		N	N	N	N	
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 with SC1-6H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 with L3-12H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)	P	P	P		P	P		P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	P	P	P		P	P		P	
Musculo-skeletal (*Superficial*)	P	P	P		P	P		P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P		P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 with SP1-5X Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult	N	N	N	N	N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 with L8-17X Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)	N	N	N		N	N		N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)	N	N	N		N	N		N	
Musculo-skeletal (*Superficial*)	N	N	N		N	N		N	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	N	N	N		N	N		N	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Devices

In Vitro Diagnostic Device Evaluation and Safety

510k K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 with SC1-4H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121888

Diagnostic Ultrasound Indications for Use

E-CUBE 15 with E3-10H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	N	N	N		N	N	N	N	
Trans-vaginal	N	N	N		N	N	N	N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (*Conventional*)									
Musculo-skeletal (*Superficial*)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121888